Special 510(k) Summary of Safety and Effectiveness: Line Extension to the Xia Spine System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	June 27, 2001

Device Identification

Proprietary Name:	Xia Spine System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	Spinal Interlaminal Fixation Orthosis, 21 CFR 888.3050 Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3060 Pedicle Screw Spinal System 21 CFR 888.3070

Predicate Device Identification

The features of the 8.5mm diameter Xia Polyaxial Screw are substantially equivalent to the features of the predicate 7.5 mm diameter Xia Polyaxial Screw, which were determined substantially equivalent via 510(k) K984251.

Device Description

The 8.5mm diameter Xia Polyaxial Screws are available in lengths ranging from 30 mm to 90 mm (in 5 mm increments). The top portion of the screw is threaded to accept a closure screw. The subject 8.5mm diameter Polyaxial Screw is identical to the 7.5 mm diameter Xia Polyaxial Screws except for the following differences: larger diameter bone thread and tapered screw tip. The subject screws are manufactured from titanium alloy.

Intended Use:

The 8.5mm diameter Xia Polyaxial Screws are intended to be used with the other components of the Xia Spine System.

Indications for Use:

The Xia Spine System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the Xia Spine System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the XIA Spine System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the XIA Spine System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

Statement of Technological Comparison:

The 8.5 mm diameter Xia Polyaxial Screws share the same material, intended use, and basic design concepts as that of the currently available 7.5 mm diameter Xia Polyaxial Screws. An engineering analysis demonstrated the comparable properties of the subject 8.5mm diameter Xia Polyaxial Screw to the predicate Xia Polyaxial Screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2001

Ms. Karen Ariemma
Howmedica Osteonics Corp.
Regulatory Affairs Specialist
59 Route 17
Allendale, New Jersey 07401

Re: K012027
Trade Name: Xia Spine System
Regulatory Number: 888.3050, 888.3060, and 888.3070
Regulatory Class: II
Product Code: MNH, KWP, KWQ, MNI
Dated: June 27, 2001
Received: June 28, 2001

Dear Ms. Ariemma:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012027

Device Name: Xia Spine System

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Ann

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Prescription Use ✓ OR Over-The-Counter Use ____ (Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number K012027